SEP - 9 2005

K051904

Section B

510(k) Summary

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K05 1904

SunTech Medical, Inc.
Abbreviated 510(k) Submission
All Purpose Cuff
510(k) Summary
27 May 2005

(1) Submitter information

Name:	SunTech Medical, Inc.
Address:	507 Airport Boulevard Suite 117 Morrisville, North Carolina 27560-8200
Telephone:	919.654.2332
FAX:	919.654.2301
Contact person:	David Gallick (Official Correspondent).
	SunTech Medical, Inc. 507 Airport Boulevard Suite 117 Morrisville, North Carolina 27560-8200 Tel: 919-654-2332 Fax: 919-654-2301
Date prepared:	20 May 2005

(2) Name of Device

Trade Name:	All Purpose Cuff
Common Name:	Blood Pressure Cuff
Classification name:	Cuff, Blood Pressure, DXQ, 870.1120

(3) Legally-marketed predicate devices

Sun Tech Medical has identified two predicate devices for the All Purpose Cuff:

CRITIKON DURA-CUF® Blood Pressure Cuff, Critikon company, LLC.

Cuff accessory for the Oscar 2 Oscillometric Ambulatory BP Recorder, SunTech Medical, Inc.

The All Purpose Cuff is substantially equivalent to these devices.

(4) Description

The All Purpose Cuff is an accessory for noninvasive blood pressure systems. It is comprised of a connector attached to tubing attached to an air tight bladder which is enclosed within an inelastic sleeve. The All Purpose Cuff comes in a range of sizes. Each is marked with the appropriate limb circumference for which the cuff is intended.

(5) Intended Use

The All Purpose Cuff is an accessory that is intended to be used with manual or automated noninvasive sphygmomanometers. It makes no diagnosis. The All Purpose Cuff is non-sterile and may be reused. It is available in pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated..

(6) Comparison to Predicate Devices

The All Purpose Cuff has the same basic construction as the predicate devices. All three devices are wrapped around the patients limb and secured by means of a hook and loop type fastener. The All Purpose cuff is made from the same material as the Ocsar2 cuffs. The All Purpose cuff is available in the same size/ranges as the CRITIKON cuff and is intended for the same patient populations.

(7) Testing and Validations

The All Purpose Cuff has been tested to the applicable requirements of the following standards and requirements documents. These tests have indicated passing results.

- AAMI SP10: 2002
- AAMI SP10:1994
- AAMI SP9:1994
- EN1060-1: 1996
- EN1060-2:1996
- EN1060-3:1997
- IEC60601-2-30:1999
- Marketing Specification, (SunTech document # 97-0037-XX-FS), version 11

(8) Conclusion

The All Purpose Cuff is equivalent in safety and efficacy to the legally-marketed predicate devices

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 9 2005

SunTech Medical, Inc.
c/o Mr. David Gallick
Vice President - Engineering
507 Airport Blvd., Suite 117
Morrisville, NC 27560-2301

Re: K051904
Trade Name: All Purpose Cuff, Model 222APC
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: July 12, 2005
Received: July 13, 2005

Dear Mr. Gallick:

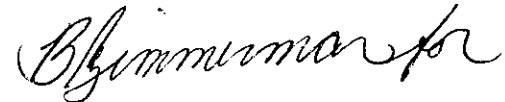
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051904

Device Name: All Purpose Cuff; Model 222APC

Indications For Use:

The All Purpose Cuff is intended to be used with a manual or automatic non-invasive sphygmomanometer to determine blood pressure parameters on pediatric and adult patients. They are not intended to be used on neonates. They are intended to be used with prescription (clinical grade) blood pressure monitors; they also could be used with Over-The-Counter (home) blood pressure monitors.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) (AND/OR) Over-The-Counter Use __X___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051904